

REMARKS

Claims 1-2 and 4-17 are pending in the application. Support for the amendment to claim 1 appears in, e.g., paragraph 76. No new matter is added. Applicants request rejoinder of withdrawn claims 15-17 as they fall within the subject matter of the group elected in the Applicants' May 4, 2010 Response to Restriction Requirement submitted.

Rejections under 35 USC § 102(b)

Claims 1 and 4 remain rejected U.S. Patent No. 3,146,169 ("Spence"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1, from which depends claim 4, has been amended to specify that the colorant in the core is blended with the active substance. Spence does not teach a tablet with a core in which the active substance is blended with a colorant. More particularly, the amendment distinguishes Figure IV of Spence, which was relied upon by the Examiner in the rejection. The Examiner asserts that components 1 and 2 of Figure IV can be considered the 'core'. Component 1 of Figure IV corresponds to an active – containing portion 1 surrounded by an inert portion 2. Claim 1, in requiring a core where the colorant is blended with the active substance, now excludes a tablet with the arrangement of component 1 and 2 shown in Figure IV.

Claims 1 and 4 are further distinguishable from Spence because they are drawn to a tablet requiring a core containing an active substance and a compression coating surrounding the core.

Spence does not describe a tablet with this feature but instead describes a tablet with a core containing an opening, or hole. Applicants note the Examiner's statement in the Office Action that "Spence teaches an inert portion that surrounds an active portion", pointing to column 1, lines 33-36 and Figure IV.

Applicants respectfully disagree that Spence describes a tablet with this feature. As Applicants explained previously, the tablet structure referenced in Figure IV of Spence includes a hole 3 that extends into a medicament portion. In addition, lines 33-36 of column 1 recite as follows:

[T]he inert portion is around or surrounds part but not all of the medicated portion; and again, it may be applied or compressed around or onto the medicated portion.

When Spence is considered in its entirety it is clear that Spence is describing a tablet in which an inert portion is around part, but not all, of the medicated portion. The paragraph in which the sentence identified by the examiner recites as follows (col. 1, lines 24-36, emphasis added):

According to the present invention in one aspect, there is provided a tablet comprising a medicated portion and a non-medicated inert portion (as hereinafter defined) **which covers part but not all of the surface of the medicated portion**. That is, there is provided a prolonged acting medicinal preparation comprising a medicated portion and a non-medicated inert portion which reduces the surface area of the medicated portion exposed to the fluids of the gastro-intestinal tract. Thus, the inert portion is around or surrounds part but not all of the medicated portion; and again, it may be applied or compressed around or onto the medicated portion.

Spence similarly refers in the remainder of its specification to a tablet in which a hole is present. For example, at col. 2, lines 15-31 Spence explains:

When the medicated portion of the tablet is readily soluble the inert portion surrounds the medicated portion except for a hole through which the contents of the medicated portion gradually pass. The correct size of the hole to achieve any desired rate of release of the medicament will depend on a number of factors, such as the ease of solubility of the medicated portion of the tablet and the thickness of the inert portion, but it may readily be ascertained for any given circumstances by means of a few simple experiments as described in more detail herein-after. More than one hole may be provided if desired. For less soluble medicaments the size of the hole may be increased until, in effect, a substantial part of the surface of the medicated portion is exposed. However, it is found that the invention is most effective when not more than 50% of the surface area of the medicated portion is exposed.

Spence additionally refers to a hole-containing medicated portion of a tablet at col. 2, lines 45-47. In addition, the method of making tablets described by Spence are constructed to include a hole (see col. 2, line 61 through col. 3, line 14. Thus, Spence does not describe a tablet in which a core is surrounded by a compression coating, which is required by the claims.

Because Spence does not teach every element of claims 1 and 4, it does not anticipate the invention now claimed. Applicants request reconsideration and withdrawal of the rejection for anticipation.

Rejections under 35 USC § 103(a)

Claims 1 and 4-6 are rejected obvious over Spence. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1, from which the remaining claims subject to the rejection depend, as amended is drawn to a tablet with a core with a core colorant combined with an active substance. Spence does not describe or suggest a tablet with these features, nor does this reference describe or suggest a tablet with a core that is surrounded by a coating.

The claimed invention provides a tablet in which a colouring agent or excipient in such tablets allows one to determine whether the core is centrally located within the core, assess the integrity of the core, and to ensure that there is no contaminating core material on or near the surface the coating (see abstract). There is no suggestion of a tablet with this feature in Spence. The integrity, location, and contamination level of a core cannot be determined using a tablet as shown in Spence the because the colorant is separated from the active agent (see discussion of Figure IV in Spence, above). For at least this reason the claims are non-obvious over Spence.

Applicants request reconsideration and withdrawal of the rejection.

Rejections over Spence in view of Thurn-Müller

The Examiner rejected claims 2, 12, and 13 as obvious over Spence, further in view of Thurn-Müller *et al.*, (U.S. Patent 5,310,578, issued on May 10, 1994) The rejection is traversed to the extent it is applied to the claims as amended. Claims 2, 12, and 13 depend from claim 1 and are non-obvious over Spence for the reasons discussed above.

According to the Examiner, Thurn-Müller teaches that “red iron oxide, aluminium silicate and calcium silicate are well known examples of pigments” (*see* Office Action, p. 7, ¶ 5). But there is no teaching, suggestion, or motivation in this reference of a tablet required by the claims. This reference, therefore, fails to overcome the deficiencies of Spence. Applicants request reconsideration and withdrawal of the rejection.

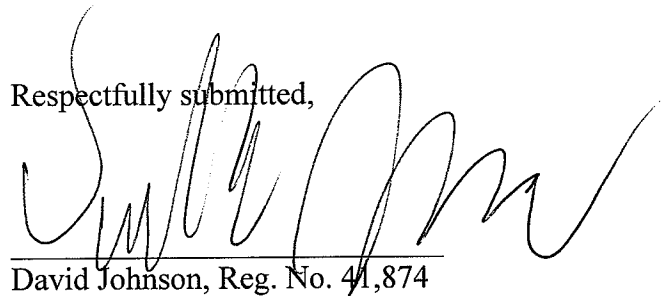
Rejections over Spence in view of Guglielmotti

The Examiner rejected claims 7, 8, and 14 as obvious over Spence, further in view of Guglielmotti *et al.*, (U.S. Patent 6,020,356, issued on February 1, 2000). The rejection is traversed.

Claims 7, 8, and 14 depend from claim 1 and are non-obvious over Spence for the reasons discussed above. Guglielmotti is cited for teaching the treatment of several conditions with bindarit and an immunosuppressant such as prednisone. However, it does not overcome the deficiencies of Spence.

Applicants submit that the application is in condition for allowance and request an action for same. A petition for an extension of time accompanies this response, along with the appropriate fee. Please charge any additional fee, or credit any overpayment of same, to Deposit Account No. 50-0311, Attorney Reference No. 28069-618N01US.

Respectfully submitted,



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